

REMARKS

This Application has been carefully reviewed in light of the Office Action mailed September 3, 2009. Claims 1-23 are pending and rejected in the Application. Applicants respectfully request reconsideration and favorable action in this case.

The Claims Satisfy the Requirements of Section 112

A. Claims 15-23 Satisfy the Requirements of Section 112, first paragraph

The Office Action rejects Claims 15-23 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Office Action states at page 2 that "there is no disclosure of quantitative analysis of data, nor is there disclosure of establishing values corresponding to a level of fluorescence from lymph nodes." Applicants respectfully traverse these rejections for at least the reasons below.

As a preliminary matter, Applicants note that Claims 15-23 are part of the original disclosure and according to the M.P.E.P. a claim limitation "in and of itself may enable one skilled in the art to make and use the claim containing the limitation." M.P.E.P. § 2164. Furthermore, other portions of the Specification as originally filed enable the limitation of "quantitizing a fluorescence characteristic." For example, FIGURES 7A through 7D and the corresponding description disclose quantitative values for "the DC (a.u.) and AC (a.u.) contrast images (background subtracted) that were simultaneously obtained when a 100µL target containing 100 fmol of ICG was positioned at increasing depths within one percent of a Liposyn® in increments of one centimeter from an illumination surface using the system of FIGURE 6." *See, e.g.*, Page 12, Lines 9-13. In addition, the Specification incorporates by reference U.S. Pat. No. 5,865,754 (Page 6, Line 18-20), which discloses various examples of quantitative data analysis. According to the M.P.E.P., information incorporated by reference "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." M.P.E.P. § 2163.07(b).

Applicants' Specification also enables the limitation, "establishing a number of values with a processor, each of the values corresponding to a level of the fluorescence characteristic at a different position within the sentinel lymph node." For example, in addition to the claims themselves, the above identified portions of Applicant's Specification, and the incorporated disclosure of U.S. Pat. No. 5,865,754, the Specification further discloses an embodiment that

“track[s] the position of the florescent target (when detected) as its depth (z) is moved within the planar (x-y) field of view.” *See, e.g.*, Page 12, Lines 16-18. As another example, Applicants’ Specification discloses how “emission light may be selectively separated from the excitation light and measured,” according to one embodiment, and that the “Camera 620 output may be processed by any suitable processor.” *See, e.g.*, Page 11, Lines 12-29.

Applicants respectfully submit that at least these example disclosures contain sufficient information regarding the subject matter of the claims so as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. For at least the above reasons, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph and full allowance of Claims 15-23.

B. Claims 5, 8, 10, 13, 14, and 15-20 Satisfy the Requirements of Section 112, second paragraph

The Office Action rejects Claims 5, 8, 10, 13, 14, and 15-20 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse for at least the reasons below.

With regards to Claim 14, Applicants appreciate the Examiner bringing to Applicants’ attention the antecedent basis issue. Applicants have amended “the imaging device” of dependent Claim 14 to recite “the imaging apparatus,” which has antecedent basis in independent Claim 7 from which Claim 14 depends. The amendment to Claim 14 renders moot the rejection and Applicants respectfully requests that the rejection be withdrawn.

With regard to Claims 5, 10, and 15, the Office Action states on page 2, “it is unclear how one can modulate an intensity to obtain light of a particular wavelength range, as the claim appears to set forth, since varying intensity is not generally associated with shifting wavelength.” Applicants respectfully disagree. Claim 15 does not recite the word “intensity.” The Office Action thus appears to base the rejection of Claim 15 entirely on a term (intensity) that does not appear in Claim 15. To the extent the Office Action is referring to the limitation, “directing into the tissue of the body near-infrared time-varying excitation light modulated to obtain a wavelength between approximately 700 nm and 900 nm,” as recited in Claim 15, Applicants respectfully requests the Examiner explain why the Examiner believes that the limitation is vague and indefinite, as is required, so that Applicants may properly respond. Applicants contend that this limitation satisfies the requirements of

Section 112. At least because the Office Action provides no proper basis for the rejection of Claim 15 under 35 U.S.C. § 112, second paragraph, Applicants respectfully request withdrawal of the rejection.

Applicants' amendments to dependent Claims 5 and 10 render moot the rejection of these claims under 35 U.S.C. § 112, second paragraph, though Applicants do not acquiesce to the correctness of the rejection. In particular, Applicants have broadened the scope of Claims 5 and 10 by removing the phrase "the intensity of the," such that amended Claim 5 recites, "further comprising modulating the excitation light to obtain a wavelength between approximately 700 nm and 900 nm" and Claim 10 recites, "a frequency generator to modulate the near-infrared time-varying excitation light to obtain a wavelength between approximately 700 nm and 900 nm." At least because the Office Action bases the rejection of Claims 5 and 10 on a term (intensity) which no longer appears in amended Claims 5 and 10, Applicants respectfully request withdrawal of the rejections of Claims 5 and 10 under 35 U.S.C. § 112, second paragraph.

With regard to the rejections of Claims 8 and 13, the Office Action appears to have incorrectly based the rejection of these claims on supposed requirements of 35 U.S.C. § 112, second paragraph. In particular, the Office Action states on pages 2 through 3 that "the group recited in [Claim 8] does not appear to set forth a further limitation" and "it is unclear what how [sic] the limitation of [Claim 13] further limits the structure of claim 7." However, "[a] claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph." M.P.E.P. § 2173.05(f). To the extent the Examiner may consider submitting new grounds of rejection under 35 U.S.C. § 112, fourth paragraph, Applicants respectfully submit that the relevant section of the M.P.E.P. states the following:

A dependent claim does not lack compliance with 35 U.S.C. 112, fourth paragraph, simply because there is a question as to (1) the significance of the further limitation added by the dependent claim, or (2) whether the further limitation in fact changes the scope of the dependent claim from that of the claim from which it depends. The test for a proper dependent claim under the fourth paragraph of 35 U.S.C. 112 is whether the dependent claim includes every limitation of the claim from which it depends. *The test is not one of whether the claims differ in scope.*

M.P.E.P. § 608.01(n) (emphasis added). Applicants respectfully submit that Claims 8 and 13 satisfy the requirements of 35 U.S.C. § 112 and Applicants respectfully requests withdrawal of the rejections.

Claims 1-14 are allowable over the proposed *Hayaski-Chance-Gratton* combination

The Office Action rejects Claims 1-6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,804,549 to Hayashi ("*Hayaski*") in view of U.S. Patent 5,673,701 to Chance ("*Chance*"). The Office Action rejects Claims 7-14 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Hayaski*, *Chance* and U.S. Patent No. 5,213,105 to Gratton et al. ("*Gratton*"). Independent Claims 1 and 6 have been amended to incorporate certain features from Claims 4 and 9, respectively.

Independent Claim 1, as amended, should be allowed at least because the cited references fail to disclose or suggest, "wherein the generated time-varying excitation light comprises a spatial distribution selected from the group consisting of a planar wave, a series of lines of illumination, concentric circles of illumination, and a ronchi rule pattern." The Office Action concedes at page 2 that *Hayaski* fails to disclose "time-varying excitation light." Because *Hayaski* fails to disclose "time-varying excitation light," *Hayaski* must also fail to disclose "wherein the generated time-varying excitation light comprises a spatial distribution selected from the group consisting of a planar wave, a series of lines of illumination, concentric circles of illumination, and a ronchi rule pattern." The *Chance* and *Gratton* references fail to atone for the deficiency of *Hayaski* regarding the above limitation. Indeed, the Office Action fails to even address a similar limitation previously recited in original dependent Claim 4. In addition to the above reasons, amended independent Claim 1 should be allowed also at least because the cited references fail to disclose or suggest, "using frequency-domain photon migration, filtering light that is not time-varying."

For at least these reasons, Claim 1 should be allowed allowable over the proposed *Hayaski-Chance* combination, as should all claims depending therefrom. Independent Claim 7, as amended, should be allowed over the proposed *Hayaski-Chance-Gratton* combination for reasons analogous to at least some of the reasons above, as should all claims depending therefrom. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a) and allowance of Claims 1-14.

Dependent Claim 11 should be allowed at least because it depends from independent Claim 7, which is allowable at least for the reasons discussed above. In addition, dependent Claim 11 should be allowed at least because the cited references fail to disclose or suggest, "wherein the one or more optical filters are selected from the group consisting of a band pass filter, a long pass filter, and a holographic notch filter." Notably the Office Action fails to specifically indicate any portions of the cited references allegedly disclosing this limitation. Indeed, the Office Action fails to even address this limitation. For at least these additional reasons, dependent Claim 11 should be allowed. Dependent Claim 12, which depends from independent Claim 7, is allowable at least for analogous reasons. Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of dependent Claims 11 and 12.

Conclusions

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stands ready to conduct such a conference at the convenience of the Examiner.

Applicants take a one-month extension of time from July 3, 2008 to August 3, 2008. The Commissioner is hereby authorized to charge the one-month extension fee in the amount of \$60.00 and any other required fees or credit any overpayments to Deposit Account No. 02-0384 of Baker Botts L.L.P.

Respectfully submitted,

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